



091470603

9-25-06

67c
SDocket No.: 20718/1204135-US8
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Letters Patent of:
David J. Bova

Patent No.: 7,011,848

Issued: March 14, 2006

For: NICOTINIC ACID COMPOSITIONS FOR
TREATING HYPERLIPIDEMIA AND
RELATED METHODS THEREFOR

Certificate
SEP 29 2006
of Correction

**REQUEST FOR CERTIFICATE OF CORRECTION
PURSUANT TO 37 CFR 1.323**

Attention: Certificate of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Upon reviewing the above-identified patent, Patentee noted typographical errors which should be corrected.

In the Specification:

At column 2, line 34, please delete the phrase "18 or 78 percent" and insert the phrase --12 or 52 percent--.

At column 15, line 34, please delete the phrase "had 18 of 23, or 78 percent" and insert the phrase --had 12 of 23, or 52 percent--.

091470603 20718/1204135-US8
OCT 2 2006
G. REED

At column 14, line 44 to column 15, line 30, please replace Table VIII with the following corrected replacement table:

TABLE VIII
A Comparison of Changes in Liver Function Tests

	DOSE								
	0	500	1000	1500	2000	2500	3000	TOTAL	
McKenney SR^bNiacin									
AST	23.8	27.9	40.4	36.6	56.5	na	97.0		
%	--	117	170	154	237	na	408		
Invention Dosage^c									
AST	24.3	na	23.7	27.5	26.6	27.6	27.8		
%	--	na	98	113	109	114	114		
McKenney SR Niacin									
AST	25.6	29.5	36.3	39.0	59.1	na	100.0		
%	--	115	142	152	231	na	391		
Invention Dosage									
ALT	21.4	na	18.7	22.6	21.3	22.4	21.8		
%	--	na	87	106	100	105	102		
McKenney SR Niacin									
ALK	95	95	106	105	136	na	135		
%	--	100	112	111	143	na	142		
Invention Dosage									
ALK	74.7	na	73.9	76.1	73.4	76.7	78.0		
%	--	na	99	102	98	103	104		
McKenney SR Niacin									
Drop	--	0	1	2	4	na	5	12	
n	--	--	--	--	--	--	--	23	
%	--	0	4	9	17	na	22	52	
Invention Dosage									
Drop	--	--	0	0	0	0	0	0	
n	--	--	26	67	97	35	15	240	
%	--	--	0	0	0	0	0	0	
1 year	--	--	15	47	77	31	15	184	
1 year	--	--	58	69	79	89	100	77	

Dosed twice-per-day as described in "A Comparison of the Efficacy and Toxic Effects of Sustained - vs. Immediate - Release Niacin in Hypercholesterolemic Patients" by McKenney et al., *Journal of the American Medical Association*, March 2, 1994; Vol. 271, No. 9, pages 672-677.

^b SR is "sustained release"

^c Dosed once-per-day at night

2001

Remarks:

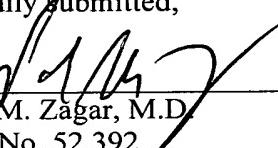
The errors were found in the application as filed by applicant. The errors now sought to be corrected are inadvertent typographical errors, the correction of which does not involve new matter or require reexamination.

Our check in the amount of \$100.00 covering the fee set forth in 37 CFR 1.20(a) is enclosed. The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Transmitted herewith is a proposed Certificate of Correction effecting such amendment. Patentee respectfully solicits the granting of the requested Certificate of Correction.

Respectfully submitted,

Dated: September 21, 2006

By: 

Paul M. Zagar, M.D.
Reg. No. 52,392
DARBY & DARBY P.C.
P.O. Box 5257
New York, New York 10150-5257
(212) 527-7700 (Tel.)
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

PATENT NO. : 7,011,848
APPLICATION NO. : 09/470,603
ISSUE DATE : March 14, 2006
INVENTOR(S) : David J. Bova

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

At column 2, line 34, please delete the phrase "18 or 78 percent" and insert the phrase --12 or 52 percent--.

At column 15, line 34, please delete the phrase "had 18 of 23, or 78 percent" and insert the phrase --had 12 of 23, or 52 percent--.

OCT - 2 2006

MAILING ADDRESS OF SENDER:
DARBY & DARBY P.C.
P.O. Box 5257
New York, New York 10150-5257

Patent No.: 7,011,848

Page 1 of 2

At column 14, line 44 to column 15, line 30, please replace Table VIII with the following corrected replacement table:

TABLE VIII
A Comparison of Changes in Liver Function Tests

		DOSE							
		0	500	1000	1500	2000	2500	3000	TOTAL
McKenney SR^bNiacin									
AST	23.8	27.9	40.4	36.6	56.5	na	97.0		
%	--	117	170	154	237	na	408		
Invention Dosage^c									
AST	24.3	na	23.7	27.5	26.6	27.6	27.8		
%	--	na	98	113	109	114	114		
McKenney SR Niacin									
AST	25.6	29.5	36.3	39.0	59.1	na	100.0		
%	--	115	142	152	231	na	391		
Invention Dosage									
ALT	21.4	na	18.7	22.6	21.3	22.4	21.8		
%	--	na	87	106	100	105	102		
McKenney SR Niacin									
ALK	95	95	106	105	136	na	135		
%	--	100	112	111	143	na	142		
Invention Dosage									
ALK	74.7	na	73.9	76.1	73.4	76.7	78.0		
%	--	na	99	102	98	103	104		
McKenney SR Niacin									
Drop	--	0	1	2	4	na	5	12	
n	--	--	--	--	--	--	--	23	
%	--	0	4	9	17	na	22	52	
Invention Dosage									
Drop	--	--	0	0	0	0	0	0	
n	--	--	26	67	97	35	15	240	
%	--	--	0	0	0	0	0	0	
1 year	--	--	15	47	77	31	15	184	
1 year	--	--	58	69	79	89	100	77	

Dosed twice-per-day as described in "A Comparison of the Efficacy and Toxic Effects of Sustained - vs. Immediate - Release Niacin in Hypercholesterolemic Patients" by McKenney et al., *Journal of the American Medical Association*, March 2, 1994; Vol. 271, No. 9, pages 672-677.

^b SR is "sustained release"

^c Dosed once-per-day at night

MAILING ADDRESS OF SENDER:
DARBY & DARBY P.C.
P.O. Box 5257
New York, New York 10150-5257

Patent No.: 7,011,848

Page 2 of 2



Application No. (if known): 09/470,603

Attorney Docket No.: 20718/1204135-US8

Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. EV834732721-US in an envelope addressed to:

Attention: Certificate of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on September 21, 2006
Date



Signature



Typed or printed name of person signing Certificate

Registration Number, if applicable

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Fee Transmittal (1 page);
Request for Certificate of Correction (Fee Required) (3 pages);
Certificate of Correction (2 pages);
Check No. 125169 in the amount of \$100.00; and
Return postcard.



Under the Paperwork Reduction Act of 1995, no person are required to respond to a collection of information unless it displays a valid OMB control number.

Complete if Known

Effective on 12/08/2004. Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).			
FEE TRANSMITTAL For FY 2005			
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27			
TOTAL AMOUNT OF PAYMENT	(\\$) 100.00	Attorney Docket No.	20718/1204135-US8

METHOD OF PAYMENT (check all that apply)

<input checked="" type="checkbox"/> Check	<input type="checkbox"/> Credit Card	<input type="checkbox"/> Money Order	<input type="checkbox"/> None	<input type="checkbox"/> Other (please identify): _____
<input type="checkbox"/> Deposit Account		Deposit Account Number: <u>04-0100</u>		Deposit Account Name: <u>Darby & Darby P.C.</u>

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

<input type="checkbox"/> Charge fee(s) indicated below	<input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee
<input type="checkbox"/> Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17	<input checked="" type="checkbox"/> Credit any overpayments

FEE CALCULATION**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

<u>Application Type</u>	<u>FILING FEES</u>		<u>SEARCH FEES</u>		<u>EXAMINATION FEES</u>		<u>Fees Paid (\$)</u>
	<u>Fee (\$)</u>	<u>Small Entity</u>	<u>Fee (\$)</u>	<u>Small Entity</u>	<u>Fee (\$)</u>	<u>Small Entity</u>	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEESFee Description

Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

<u>Total Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>	<u>Multiple Dependent Claims</u>
- =	x	=		<u>Fee (\$)</u> <u>Fee Paid (\$)</u>

HP = highest number of total claims paid for, if greater than 20.

<u>Indep. Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>	
- =	x	=		

HP = highest number of independent claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

<u>Total Sheets</u>	<u>Extra Sheets</u>	<u>Number of each additional 50 or fraction thereof</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
- 100 =	/50	(round up to a whole number) x	=	

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)	
Other (e.g., late filing surcharge): 1811 Certificate of correction	100.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent)	52,392	Telephone	(212) 527-7700
Name (Print/Type)	Paul M. Zagar			Date	September 21, 2006